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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,334	04/09/2001	Elmar Peschke	1348	8721

7590 11/30/2004

Striker Striker & Stenby
103 East Neck Road
Huntington, NY 11743

EXAMINER

CHISM, BILLY D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,334

Applicant(s)

PESCHKE ET AL.

Examiner

B. Dell Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-17 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Withdrawal of Objections and Rejections

1. This office action is in response to Applicants' papers filed 3 September 2004. Claims 11-17 are pending with claims 14-17 withdrawn from consideration. The rejections and/or objections made in the prior office action dated 13 May 2004, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 3 September 2004 will be addressed to the extent that they pertain to the present grounds of rejection.

2. (Maintained) Claims 14-17 remain withdrawn from consideration for those reasons in the previous office action. The claims 14-17 are drawn to an invention that has not been prosecuted/searched on the merits or presented/searched on the merits. The art rejection in office action filed on 26 July 2002 was to an indefinite claim and the rejection never states the word "method". The rejection revolved around the "use of" aspect of the prior art and the "use of" indefiniteness of the instant claim. Applicants are interpreting the rejection as acquiescence to in vitro use, and this interpretation is not the case. Furthermore, Applicants argue unity practice under PCT allows for the addition of different inventions since this case is a National State (371) entry. Unfortunately, there would be no unity of invention here since the technical feature of melatonin is well known in the art as was indicated in the first office action on the merits. For all these reasons and those of the previous office action, the claims 14-17 remain withdrawn from consideration.

Claim Rejections - 35 USC § 112

3. (Maintained) Claims 11-13 remain rejected under 35 U.S.C. 112, first paragraph, because the specification lacks enablement for the claimed in vivo methods. For those reasons of the previous office action and those presented here, the claims lack enablement for the in vivo administration for treating hyperinsulinaemia.

Applicants' arguments regarding US patents as comparative reasons for enablement is not persuasive. The prosecution history of a completely unrelated patent or patent application has no bearing on the instant prosecution process or reasoning. Therefore, those arguments are moot with respect to obviating the instant enablement rejection.

Applicants argue the disclosure of dosage ranges and application formulations enable the invention, however, this does not offer enough toward predictability of efficacy of the method toward treatment of hyperinsulinaemia. This goes toward written description requirement but does not breath enablement into the claimed invention.

The examiner wants to point out, as in the previous office action, that Bailey *et al.* is not being considered on its merits, however, Bailey *et al.* is being relied on as casting doubt on the in vivo predictability of melatonin use in hyperinsulinaemia. However, the Applicants do not address this point of view.

For these reasons and those reasons of the previous office action, the rejection is maintained.

Claim Rejections - 35 USC § 103

4. (Withdrawn) Rejection of Claims 11-13 under 35 U.S.C. 103(a) as being unpatentable over Richardson *et al.* (US 6,207,190 B1) is withdrawn as obviated wherein the Applicants have demonstrated that the instant application has priority over the patent.

Conclusion

5. No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

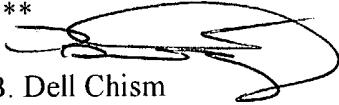
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on 571-272-0974. The fax phone number for

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the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism



CHRISTOPHER R. TATE
PRIMARY EXAMINER